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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/732,638	12/08/2000	Andreas Castan	10806-151	2602

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EXAMINER

SISSON, BRADLEY L

ART UNIT PAPER NUMBER

1655

DATE MAILED: 12/18/2001

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary**Application No.**

09/732,638

Applicant(s)

CASTAN, ANDREAS

Examiner

Bradley L. Sisson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 September 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-27 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method set forth at pages 6 and 7 of the disclosure, does not reasonably provide enablement for achieving the unexpected physiological result when culturing is conducted under different parameters; e.g. different carbon source is used, nor does the specification enable unexpected results with respect to the application of an oscillating agitation speed when any type of agitation means are applied nor where any speed of agitation is used. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. See the Office action of 22 June 2001 for the basis of the rejection.

Response to arguments

3. At page 4-6 of the response of 26 September 2001, hereinafter the response, it is asserted that the specification, as filed, adequately enables the claimed invention, with attention being directed to page 1, lines 6-10, and page 5 lines 16-23.
4. Applicant's arguments have been fully considered and have not been found to be persuasive towards the withdrawal of the rejection for while the specification does set forth

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general guidelines by which culturing of microorganisms may proceed, such statements have not been found to support the reproduction of the unexpected results obtained in the disclosed experiment where *E. coli* (W3110), transfected with a pBR plasmid encoding rhGH, were cultured under the conditions specified in the subject disclosure. It is noted with particularity that applicant asserts that the results obtained are unexpected. It is further noted that the results are the product of the manipulation of physiological systems in an artificial environment. The court has recognized physiological conditions as being highly unpredictable and that broader protection for inventions based upon such require greater levels of disclosure. In support of this position, attention is directed to *In re Fisher* 166 USPQ 18 (CCPA, 1970):

In cases involving predictable factors, such as that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

In the present case applicant is seeking protection for a generic method that encompasses the use of any and all manner of microorganisms for the recombinant production of any and all manner of products. As stated above, the specification has been found to set forth but a single species where an unexpected result was obtained. There is insufficient disclosure to enable the practice and culmination of this unexpected result over the broad genus of products and microorganisms encompassed presently.

Similarly, the claimed method encompasses a method whereby the unexpected result is obtained by only changing the speed at which the culture is stirred. A review of the disclosure fails to find support for where the unexpected result was obtained by simply changing the stirring speed, however, small, so to result in the unexpected result.

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For purposes of examination the method of claim 1 has been interpreted as encompassing a method characterized by an "oscillation variation of stirring speed" where the oscillation can be of any magnitude, and where the components of the culture media maybe increased continually and/or be allowed to go to exhaustion. Support for this interpretation is based upon the presence of the phase: "wherein the cultivation is carried out by the addition of the organic carbon source in oscillation feed and/or by oscillation variation of stirring speed..." (emphasis added). A review of the disclosure fails to locate an enabling disclosure for such embodiments.

5. For the above reasons, and in the absence of convincing evidence to the contrary, the rejection is maintained and is also applied against new claims 21-27.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

7. Claims 1-27 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

8. Bylund et al., discloses a method for the recombinant production of peptides by fed-batch cultivation of a microorganism in a bioreactor. The microorganism *E. coli* was used to culture rhGH. Figure 2 clearly depicts the different oscillations of concentration of organic carbon source. The publication discloses that it was the result of the combined efforts of the various individuals. The contact person for the work was that of G. Larsson whilst a co-author was that of the applicant in the subject application. Given that the first author, the contact person were all

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of a different institution from that of applicant, and that the works cites that it was the result of the combined efforts of all individuals, a reasonable question exists as to what inventive contribution the other individuals, e.g., G. Larsson and F. Bylund had toward the claimed invention.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is 703-308-3978. The examiner can normally be reached on Monday through Friday from 6:30 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703-308-1152. The fax phone numbers for the

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organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-0294.



Bradley L. Sisson
Primary Examiner
Art Unit 1655

bls
December 14, 2001